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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,284	08/18/2005	Jorg Mayer	ZIMR/0016	2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,284	MAYER ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/25/05, 9/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim

filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on March 25, 2005 and September 27, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1, 18 and 24, claim language recites "fast-release capsules". The term "fast-release" is a relative term which renders the claim indefinite. The term "fast-release" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

With respect to claim s 18-23, claim language recites "physiologically acceptable excipients". It is unclear what applicant means by "physiologically acceptable" when describing the excipients. Please clarify.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 7, 10, 18, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khankari et al. (US 6,024,981) in view of Caruso et al. (WO 00/77281).

With respect to claims 1, 7, 18 and 19, Khankari et al. discloses a solid dosage form (tablet) for oral administration comprising a coherent matrix with a disintegration time of less than 2 min. (col. 3, lines 36-40; col. 10, lines 52-58), wherein the matrix comprises an active ingredient (col. 4, lines 35-65) which is slightly soluble in a physiological fluid. (Examiner notes that Khankari et al. gives an example of the active ingredient being folic acid, and it is well known in the art that folic acid is water soluble, thus is soluble to some degree in saliva). Khankari et al. discloses mixing the active ingredient with matrix-forming, physiologically acceptable excipients (fillers, disintegrants, binders etc.) to provide a mixture and forming the mixture into dose units (tablet) (col. 2, lines 42-63), and the active ingredient is in the form of fast-releasing microcapsules (col. 5, lines 61-62; col. 7, lines 2-3; col. 8, lines 12-15). Khankari et al. disclose the microcapsules comprising a core (microparticle) and a shell (coating) (col. 6, lines 25-27), wherein the core comprises the slightly soluble active ingredient. Since

the microcapsule is considered to be rapid-releasing, the shell is also considered to have a high permeability. Khankari et al. fails to expressly disclose the shell of the microcapsules comprising of at least one polyelectrolyte and a counter ion to the polyelectrolyte. Caruso et al. teaches using particles having shell walls made of alternating layers of polyelectrolytes of opposite charges (pg. 11, lines 5-15). Caruso et al. further teaches controlling the permeability of the capsule by controlling the number of layers and by the selection of the polyelectrolytes used for the shell (pg. 11, lines 21-25; pg. 12, lines 17-18). It would have been obvious to one of ordinary skill in the art modify the composition of the shell of the microcapsule, as taught by Caruso et al., for the predictable result of controlling the release rate of the microcapsule.

With respect to claim 5, the modified Khankari et al. discloses the slightly soluble active ingredient is an antihypertensive (col. 4, line 42).

With respect to claim 10, the modified Khankari et al. discloses the matrix is produced by compressing a material selected from at least one of powder and granules (col. 6, lines 57-59).

With respect to claim 23, the modified Khankari et al. discloses the active ingredient is a therapeutic (col. 5, lines 17-21).

Claims 1-3, 5-10, 18-20, 22-24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (US 2002/0106403) in view of Caruso et al. (EP 1 116 516).

With respect to claims 1, 2, 6-9, 18, 19, 22, 24, 27 and 29, Parikh et al. discloses a solid dosage form for oral administration comprising a coherent matrix with a disintegration time of less than 30 seconds [0024], wherein the matrix comprises an active ingredient which is slightly soluble in a physiological fluid (poorly soluble) [0010]. Parikh et al. discloses mixing the active ingredient with matrix-forming, physiologically acceptable excipients to provide a mixture and forming the mixture into dose units (tablet) [0022] and the active ingredient is in the form of fast-releasing microcapsules (phospholipid-coated microparticles) [0012], [0025]. Parikh et al. disclose the microcapsules comprising a core (microparticle) and a shell (coating), wherein the core comprises the slightly soluble active ingredient. Since the microcapsule is considered to be rapid-releasing, the shell is also considered to have a high permeability. Parikh et al. further discloses the microcapsules having an average size of less than 10μm [0017]. Parikh et al. fails to expressly disclose the shell of the microcapsules comprising of at least one polyelectrolyte and a counter ion to the polyelectrolyte. Caruso et al. discloses using microparticles having shell comprising an amphiphilic (phospholipid) and alternating layers of polyelectrolytes of opposite charges, where the polymer layers are self-assembled by means of electrostatic layer-by-layer deposition [0009], [0019]. Caruso et al. further discloses controlling the permeability and porosity of the capsule by controlling the number of layers and by the selection of the polyelectrolytes used for the shell [0032], [0036]. It would have been obvious to one of ordinary skill in the art modify the composition of the shell of the microcapsule, as taught

by Caruso et al., for the predictable result of controlling the release rate of the microcapsule.

With respect to claim 3, the modified Parikh et al. discloses the release of active ingredient is virtually complete within 1 minute [0025].

With respect to claim 5, the modified Parikh et al. discloses the slightly soluble active ingredient is an antihypertensive or a sedative [0013].

With respect to claim 10, the modified Parikh et al. discloses the matrix is produced by compressing a material selected from at least one of powder and granules [0022].

With respect to claim 11, the modified Parikh et al. discloses the matrix is produced by freeze-drying a substance selected from at least one of a fluid and a highly viscous composition [0011].

With respect to claim 20, the modified Parikh et al. discloses mixing the mixture with a liquid carrier (aqueous medium) to provide a solution, wherein forming the mixture into dose units includes dividing and freeze-drying the solution [0018]-[0020].

With respect to claim 23, the modified Parikh et al. discloses the active ingredient is a therapeutic [0017].

Claims 4, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. in view of Caruso et al. and further in view of Green et al. (US 2001/0055611).

With respect to claim 4, the modified Parikh et al. addresses all the limitations of claim 1, and further discloses the matrix can include mannitol and gelatin [0018]. The modified Parikh et al. fails to expressly disclose the content of gelatin and mannitol being in a ratio of 1:1 to 1:3. Green et al. illustrates in Example 2, a formulation comprising microcapsules (coated paracetamol) and gelatin and mannitol at a ratio close to 1:1. It would have been obvious to one of ordinary skill in the art to modify the ratio of the gelatin and mannitol in order to provide an optimum rapidly disintegrating solid oral dosage form that does not have an unacceptable taste (does not rely on the use of sweeteners and flavoring agents), as taught by Green et al. [0048]. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 25, the modified Parikh et al. discloses the slightly soluble active ingredient is an antihypertensive or a sedative [0013].

With respect to claim 28, the modified Parikh et al. discloses the shell (coating) of the microcapsules comprise a lipid layer (phospholipid) [0025].

Claims 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. in view of Caruso et al. and further in view of Virgalitto et al. (US 2005/0089548).

With respect to claim 12, the modified Parikh et al. addresses all the limitations of claim 1, however fails to expressly disclose the matrix is produced by solidifying a

composition which has been spread out into a film. Virgalitto discloses microcapsules containing active ingredients, such as pharmaceutical active ingredients, in an edible film (matrix) [0012], [0043]. Vigalitto further discloses the matrix is produced by solidifying a composition which has been spread out into a film [0074]. It would have been obvious to one of ordinary skill in the art to modify the method of making the matrix in order to create an alternative oral dosage form for patients that are unable or have a difficult time swallowing conventional oral dosage forms, as taught by Vigalitto [0002].

With respect to claim 21, the modified Parikh et al. addresses all the limitations of claim 18, however fails to expressly disclose mixing the mixture with a liquid carrier (inherent to aqueous solution) to provide a solution, wherein forming the mixture into dose units includes spreading the solution into a film and drying the film. Vigalitto discloses the edible film is formed by mixing the mixture (microcapsules and excipients) with a liquid carrier to provide a solution, spreading the solution into a film and drying the film [0074], [0076]. It would have been obvious to one of ordinary skill in the art to modify the method of making the oral dosage form in order to create an alternative oral dosage form for patients that are unable or have a difficult time swallowing conventional oral dosage forms, as taught by Vigalitto [0002].

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Siebert et al. (US 6,368,625) discloses a tablet that disintegrates within 2 minutes comprising microcapsules.

Samejima et al. (US 4,462,982) discloses rapid-releasing microcapsules.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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